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18 APR 2006

Dkt. 69395-A-PCT-US/JPW/JW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Vered Rosenberger, et al.  
U.S. Serial No. : Not Yet Known (national stage of PCT  
International Application No.  
PCT/US2004/036172)  
Filed : Herewith  
For : NANOPARTICLES FOR DRUG DELIVERY

1185 Avenue of the Americas  
New York, New York 10036  
April 27, 2006

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In order to ensure compliance with applicants' duty of disclosure under 37 C.F.R. §1.56 and §1.97(a)-(d), applicants request that the following documents be considered and made of record in the above-identified application which is listed on Form PTO-1449, attached hereto as **Exhibit A**:

1. Almeida AJ, Rune S, and Müller RH. (1997) Peptide-loaded Solid Lipid Nanospheres. *Int. J. Pharm.* 149(2): 255-265 (abstract only) (**Exhibit 1**);
2. Cui Z and Mumper RJ. (2002) Genetic Immunization using Nanoparticles Engineered from Microemulsion Precursors. *Pharm. Res.* 19(7): 939-946 (**Exhibit 2**);
3. Cui Z and Mumper RJ. (2002) Coating of Cationized Protein on Engineered Nanoparticles Results in Enhanced Immune Responses. *Int. J. Pharm.* 238: 229-239 (**Exhibit 3**);
4. Cui Z and Mumper RJ. (2003) Microparticles and

Nanoparticles as Delivery Systems for DNA Vaccines.  
*Crit. Rev. Ther. Drug Carrier Syst.* 20(2&3): 103-137  
**(Exhibit 4);**

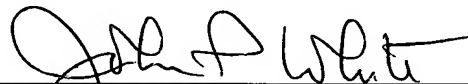
5. Lowe PJ and Temple CS. (1994) Calcitonin and Insulin in isobutylcyanoacrylate Nanocapsules: Protection against Proteases and Effect on Intestinal Absorption in Rats. *J. Pharm. Pharmacol.* 46(7): 547-552 (abstract only)  
**(Exhibit 5);**
6. Oyewumi MO and Mumper RJ. (2002) Engineering Tumor Targeted Gadolinium Hexanedione Nanoparticles for Potential Application in Neutron Capture Therapy. *Bioconjug. Chem.* 13(6): 1328-1335 **(Exhibit 6);**
7. Oyewumi MO and Mumper RJ. (2002) Gadolinium Loaded Nanoparticles Engineered from Microemulsion Templates. *Drug Dev. Ind. Pharm.* 28(3): 317-328 (abstract only)  
**(Exhibit 7);**
8. Sakuma S, Ishida Y, Sudo R, Suzuki N, Kikuchi H, Hiwatari K-I, Kishida A, Akashi M, and Hayashi M. Stabilization of Salmon Calcitonin by Polystyrene nanoparticles having Surface Hydrophilic polymeric Chains, Against Enzymatic Degradation. *Int. J. Pharm.* 159(2): 181-189 **(Exhibit 8);**
9. International Search Report issued by the International Searching Authority (ISA/US) on March 11, 2005 in connection with International Application No. PCT/US2004/036172 **(Exhibit 9);**
10. U.S. Patent No. 6,514,938 B1 (GAD et al.), published February 4, 2003 **(Exhibit 10);**
11. U.S. Patent No. 6,355,270 B1 (FERRARI et al.), published March 12, 2002 **(Exhibit 11);**

12. U.S. Patent Application Publication No. 2004/0178388 A1 (MUMPER et al.), published September 16, 2004 (**Exhibit 12**);
13. U.S. Patent Application Publication No. 2005/0170004 A1 (ROSENBERGER et al.), published August 4, 2005 (**Exhibit 13**);
14. Written Opinion of the International Searching Authority issued by the International Searching Authority (ISA/US) on March 11, 2005 in connection with International Application No. PCT/US2004/036172 (**Exhibit 14**); and
15. International Preliminary Report on Patentability (Chapter II of the Patent Cooperation Treaty) issued by the International Preliminary Examining Authority (IPEA/US) on July 1, 2005 in connection with International Application No. PCT/US2004/036172 (**Exhibit 15**).

Copies of documents numbers 1-15 are attached hereto as **Exhibits 1-15**, respectively.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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Substitute for form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	NOT YET KNOWN
		Filing Date	Herewith <b>10/5/77</b>
		First Named Inventor	Vered Rosenberger
		Art Unit	
		Examiner Name	
Sheet 1	of 3	Attorney Docket Number	69395-A-PCT-US/JPW/JW

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>2</sup>
	1	Almeida AJ, Rune S, and Müller RH. (1997) Peptide-loaded Solid Lipid Nanospheres. <i>Int. J. Pharm.</i> 149(2): 255-265 (abstract only)	
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	14	Written Opinion of the International Searching Authority issued by the International Searching Authority (ISA/US) on March 11, 2005 in connection with International Application No. PCT/US2004/036172	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Applicants: Vered Rosenberger, et al.  
U.S. Serial No. NOT YET KNOWN  
Filed: Herewith (as §371 national stage  
of PCT/US2004/036172)  
**Exhibit A**

**Complete if Known**

**(Use as many sheets as necessary)**

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NOT YET KNOWN
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Vered Rosenberger

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND**

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APR 27 2006

PTO/SB/08B (07-05)

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

## **Complete if Known**

Application Number	NOT YET KNOWN 577182
Filing Date	Herewith
First Named Inventor	Vered Rosenberger
Art Unit	
Examiner Name	
Attorney Docket Number	69395-A-PCT-US/JPW/JW

Sheet 3 of 3

## **NON PATENT LITERATURE DOCUMENTS**

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	15	International Preliminary Report on Patentability (Chapter II of the Patent Cooperation Treaty) issued by the International Preliminary Examining Authority (IPEA/US) on July 1, 2005 in connection with International Application No. PCT/US2004/036172	

Examiner  
Signature

Date  
Considered

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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